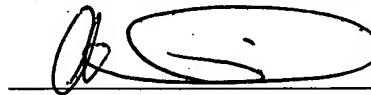




PATENT

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Alex Martinez

Applicant : Peter Gibson, et al.
Application No. : 10/820,444
Filed : April 8, 2004
Title : IMPLANT MAGNET SYSTEM

Grp./Div. : 3762
Examiner : N/A

Docket No. : 52379/DBP/R178

**LETTER FORWARDING CERTIFIED
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Enclosed is a certified copy of Australia Patent Application No. 2003901696, which was filed on April 9, 2003, the priority of which is claimed in the above-identified application.

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By 
D. Bruce Prout
Reg. No. 20,958
626/795-9900

DBP/aam
Enclosure: Certified copy of patent application



Australian Government

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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901696 for a patent by COCHLEAR LIMITED as filed on 09 April 2003.

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WITNESS my hand this
Sixteenth day of April 2004

A handwritten signature in black ink, appearing to read "J. Billingsley".

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES



AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Implant magnet system

The invention is described in the following statement:

Field of the Invention

The present invention relates to a cochlear implant and in particular to an MRI-compatible implantable component of a cochlear implant.

5

Background Art

In many people who are profoundly deaf, the reason for deafness is absence of, or destruction of, the hair cells in the cochlea which transduce acoustic signals into 10 nerve impulses. These people are unable to derive suitable benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because there is damage to or absence of the mechanism for nerve impulses to be generated from sound in the normal manner.

15 It is for this purpose that cochlear implant systems have been developed. Such systems bypass the hair cells in the cochlea and directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

20 Typically, cochlear implant systems have consisted of essentially two components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a stimulator/receiver unit. Traditionally, both of these components have cooperated together to provide the sound sensation to a user.

25

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter coil.

30

The coded signal output by the speech processor is transmitted transcutaneously to the implanted stimulator/receiver unit situated within a recess of the temporal bone of the user. This transcutaneous transmission occurs via the external transmitter coil which is positioned to communicate with an implanted receiver coil provided with the 35 stimulator/receiver unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted stimulator/receiver unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with 5 varying degrees of success.

The implanted stimulator/receiver unit traditionally includes a receiver coil that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an 10 intracochlear electrode assembly which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The commonly accepted method of providing the implanted stimulator with 15 power and information is to transmit RF-power via an inductively coupled coil system. In such a system, the external transmitter coil is usually positioned on the side of a user's head directly facing the implanted coil of the stimulator/receiver unit to allow for the transmission of the coded sound signal and power from the speech processor to the implanted unit. Such transmitters usually have a coil formed by a small number of 20 turns of a single or multi-strand wire and a magnet at or near the hub of the coil. The magnet holds the transmitter coil in place due to magnetic attraction with a magnet of the implanted unit.

Unfortunately, the implanted magnet poses problems for those cochlear implant 25 recipients that may be required to undergo magnetic resonance imaging (MRI). In this regard, although studies have indicated that MRI presents no major risk to such recipients, the magnetic fields used in MRI procedures have been shown to exert a torque force on the implanted magnet. This torque force, if significantly large, such as may be the case if a high field strength MRI is undertaken, has the potential to cause 30 undesirable consequences such as dislodgement of the magnet from its casing as well as discomfort to the recipient. There is also the potential for significant distortion of the image obtained by MRI due to the presence of the magnet in the recipient's head, which may significantly negate the usefulness of the process.

35 The applicant has developed an implantable component of a cochlear implant system that, while not specifically designed to allow removal, has been constructed so

as to allow removal of the magnet from the implantable component so that the recipient can then undergo MRI scanning. In this regard, a small incision may be made over the implant site to access the location of the magnet. A cut is then made in the silicone supporting the magnet and the coil, and the magnet is then removed using a suitable 5 instrument, such as a surgical pick. Once the magnet has been removed, the incision is covered by a sterile bandage and the MRI procedure completed. The magnet can then be replaced before the incision is closed.

10 While this implant enables a recipient to undergo an MRI procedure without risk of dislodgment of the magnet, it may not be desirable for individuals requiring multiple MRI images over extended periods.

15 The present invention aims to provide an implant which addresses the problems of the prior art.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the 20 field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

25 Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

30 It is a preferred feature of the present invention to provide an arrangement that prevents any or at least relatively substantial movement of the magnet of a transcutaneous transmitter/receiver system, such as a cochlear implant system, whilst a recipient is undergoing MRI scans of relatively low field strengths whilst also allowing relatively easy removal of the magnet from within the implantee, if necessary, such as 35 when the recipient is to undergo MRI scans of relatively high field strengths.

According to a first aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

5 the system being characterised in that the magnet of the implantable receiver component is housed within a suitable biocompatible flexible mounting, said mounting have one or more indicia thereon or therein that identify the location of the magnet
10 within the mounting.

In this aspect, the mounting can be formed of a suitable biocompatible silicone material. In one embodiment, the indicia can comprise a indented ring formed in the body of the silicone. In another embodiment, the indicia can comprise two or more
15 holes formed in the silicone. The ring or holes act as guides to a surgeon having to cut the magnet from the mounting. That is, they identify where the mounting should be cut to allow removal of the magnet held therein.

According to a second aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

20 25 the system being characterised in that an outer surface of the magnet, or a casing for the magnet, of the implantable receiver component has an engagement surface formed therein adapted to engage with a complementary engagement surface formed in a mounting of the implantable component.

30 35 In this aspect, the engagement surface can be a screw thread. The complementary engagement surface can also be a screw thread that is formed in the mounting. In one embodiment, the mounting has a ring member mounted therein, with the internal surface thereof having the thread as defined herein. The ring member can be made of a ceramic or plastics material. The mounting can be formed from a suitable biocompatible silicone.

In one embodiment, the magnet can be screwed into or otherwise engaged with the ring member in the mounting. If necessary, the magnet can then be unscrewed from the mounting. In one embodiment, an outer surface of the magnet or a casing thereof can have a slot formed therein that can receive a tool, such as a screwdriver or the like,

5 to facilitate turning of the magnet and its removal from the mounting.

In another embodiment of this aspect, the engagement surface can be a shaped abutment designed to cause a friction fit engagement between the engagement surface of the magnet and the complementary engagement surface formed in the mounting of

10 the implantable component. In this embodiment, the outer surface of the magnet, or casing of the magnet, can be shaped in a specific configuration, allowing for insertion of the magnet or part of the magnet into the mounting element. In this regard, the complementary engagement surface will be compatible with the shape of the outer surface of the magnet or magnet casing such that the outer surface can pass through the

15 mounting element. Once the outer surface of the magnet or magnet casing has been at least partially inserted into the mounting element, the magnet or magnet casing may be rotated, for example a $\frac{1}{4}$ or $\frac{1}{2}$ turn, thereby causing the shape of the engagement surface of the magnet or magnet casing to no longer be compatible with the shape of the complementary engagement surface of the mounting element. This thereby

20 provides an interference fit preventing inadvertent removal of the magnet from the mounting element. In this embodiment, the magnet may be easily removed by merely rotating the magnet the appropriate amount such that the shape of the engagement surface of the magnet means is compatible with the shape of the complementary engagement surface of the mounting element, thereby allowing easy removal of the

25 magnet.

Preferably, a spring-type force can be provided to aid in the interference fit by providing a bias force between the engagement surfaces of the magnet and the mounting element, such that when the two surfaces are in non-alignment, the magnet

30 will be securely held in place. Such a biasing force can be provided by placing a spring means or spring member in the mounting element for receiving the magnet, or by providing a compressive material such as silicone within the mounting, that is compressed once the magnet is inserted into the mounting and provides a force that biases the magnet against the mounting element.

According to a third aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a

5 magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

the system being characterised in that the magnet of the implantable receiver component is housed within a pocket formed in a suitable biocompatible flexible mounting, said pocket having a restricted opening formed therein through which the

10 magnet can be inserted but which is sized to retain the magnet within the pocket during normal use.

In one embodiment, the opening of the pocket is formed in a sidewall of the mounting.

15

According to a fourth aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a

20 magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

the system being characterised in that the magnet of the implantable receiver component is housed within a recess formed in a suitable biocompatible flexible mounting, said recess being adapted to be located adjacent the skull of the recipient in

25 use thereby ensuring the magnet is held in the recess between the receiver component and the skull of the recipient.

In one embodiment, the magnet can be removed from the recess by incising the skin of the recipient and then gently lifting the receiver component away from the skull

30 a distance sufficient to allow a surgeon to reach under the receiver component and remove the magnet from the recess.

In the third and fourth aspects, the mounting can be formed of a suitable biocompatible material, such as silicone.

35

According to a fifth aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, the external transmitter unit having a magnet positioned therein and the implantable receiver component having a magnetised insert positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

5 the magnetised insert of the implantable receiver component having a first end and a second end and increasing in width away from said first end towards said second end, the first end being adapted to be positioned closer to the skin of the recipient to ensure self-centring of the magnet of the external transmitter unit with the magnetised insert of the receiver component.

10 In one embodiment, the magnetised insert can be conical or frusto-conical in form. The magnetised insert can be mounted in a non-magnetic support within the receiver component. In one embodiment, the support can be a titanium case. In another embodiment, a suitable ceramic or plastics material stop member can lock the insert in the receiver component.

15 While the insert can be removable, the use of a magnetised insert rather than a magnet has the advantage of reducing the magnetic force on the receiver component during an MRI scan if it is left in place.

20 According to an sixth aspect, the present invention is a magnetic alignment system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;

25 the system being characterised in that the implantable receiver component is detachably connectable to an implantable tissue stimulator device.

30 In one embodiment of this aspect, electrical connection is made between the receiver component and the tissue stimulator device when the component is connected to the stimulator device. In this embodiment, a pin and socket arrangement can be used to provide the electrical connection. Once connection is made, the pin and socket

arrangement is preferably constructed such that there is no ingress of bodily fluids into either the stimulator device or the receiver component. In one embodiment, the socket can be mounted to the stimulator device and the pin or pins to the receiver component. An arrangement where the socket is part of the receiver component and the pin or pins are part of the stimulator device can be equally envisaged.

5 If the recipient is to undergo an MRI scan, an incision can be made in the recipient, and the receiver component detached from the tissue stimulator device. The entire receiver component, as defined in this aspect, is then removed rather than just the
10 magnet. Once the MRI scan is complete, the receiver component can be re-implanted and the necessary connection again made between the receiver component and the stimulator device.

According to a seventh aspect, the present invention is a magnetic alignment
15 system for a transcutaneous transmitter/receiver system, said magnetic alignment system comprising an external transmitter unit and an implantable receiver component, both the external transmitter unit and the implantable receiver component having a magnet positioned therein to allow transcutaneous alignment of said external transmitter unit and said implantable receiver component;
20 the system being characterised in that the magnet is removably held within the receiver component by one or more clips or other manipulable retaining devices.

In one embodiment, the clips can be mounted on the receiver component and adapted to engage the magnet positioned therein or thereon. In another embodiment,
25 the clips can be mounted to the magnet or a casing thereof and are engageable with the receiver component. The clips are preferably manipulable by a surgeon. In another embodiment, the clips can be manipulable by a surgeon using one or more tools.

The magnetic alignment system is preferably part of a cochlear implant system
30 wherein the external transmitter unit is positioned on the side of the recipient's head and wherein the implantable receiver component is positioned subcutaneously and in alignment with the external transmitter unit.

The external transmitter unit may comprise a transmitter coil which is preferably
35 adapted to provide in combination with the implantable receiver component, a

transcutaneous radio (RF) frequency link between the external componentry of the cochlear implant and the implanted componentry thereof.

The implantable receiver component of the system preferably comprises at least

- 5 a receiver coil. Unless otherwise described, the receiver component also preferably comprises a housing for a stimulator means. The receiver coil typically comprises a wire antenna coil. The antenna coil may be comprised of at least one and preferably two turns of electrically insulated platinum or gold wire.
- 10 The electrical insulation of the antenna coil may be provided by a flexible silicone moulding and/or silicone or polyurethane tubing.
- 15 The housing of the stimulator means is preferably implantable in a recess of the temporal bone adjacent the ear of an implantee. The housing is preferably formed from a biocompatible material or has a biocompatible coating and may be coated with a layer of silicone or parylene.
- 20 The antenna coil is preferably external of the housing. Unless otherwise defined, electrical connection between the antenna coil and the implantable componentry within the housing may be provided by one or two hermetic and electrically insulated feedthroughs.
- 25 The antenna coil of the implantable component preferably acts as part of the radio frequency (RF) link to allow transcutaneous bidirectional data transfer between the implantable component and external components of the system. The radio frequency signals can comprise frequency modulated (FM) signals. While described as a receiver coil, the receiver coil may transmit signals to the external transmitter coil which receives the signals.
- 30 Unless otherwise described, the magnet or the magnetic material of the implantable receiver component is preferably positioned within the insulation material of the antenna coil, for example within the silicone of the antenna coil and preferably centrally of the antenna coil.

As mentioned above, in use the implantable receiver component is preferably positioned, together with the housing, subcutaneously within a recess in the temporal bone of a recipient.

5 In the embodiment of the invention wherein the magnetic alignment system forms part of a cochlear implant, a first electrode assembly, adapted to be inserted in the cochlea of the implantee, preferably extends outwardly from the housing of the stimulator means of the implantable receiver component.

10 The first electrode assembly preferably comprises a carrier member having a leading end that is insertable into a cochlea of an implantee and a trailing end distal the leading end. The elongate carrier member preferably has a plurality of electrodes mounted thereon. In one embodiment, the electrodes are mounted in a longitudinal array. Each of the electrodes have at least one wire, and preferably at least two, 15 extending from each electrode back towards the trailing end of the carrier member.

Particularly, the carrier may have 22 electrodes. In another embodiment, the carrier member may have 30 electrodes. The electrodes are preferably formed from a biocompatible electrically conducting material, such as platinum.

20 In a preferred embodiment, a second electrode assembly also extends outwardly from the housing of the stimulator means. While it can be envisaged that the second electrode assembly could also be insertable in the cochlea, it is preferred that the second electrode assembly has one or more electrodes thereon and is adapted to be 25 implantable external of the internal passages, such as the scala tympani, of the cochlea.

The present invention thereby provides a magnetic alignment system which enables a recipient to undergo an MRI procedure without removing the magnet of an implant, such as a cochlear implant, or provides a system enabling easy removal of the 30 magnet to facilitate an MRI procedure at relatively higher field strengths. Such a system is particularly useful for those recipients requiring regular MRI scans.

Brief Description of the Drawings

35 By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Figure 1 is a pictorial representation of a cochlear implant system;

5 Figure 2 depicts views of another arrangement for mounting the magnet in the receiver component according to the present invention;

Figures 3a and 3b depict a still further arrangement for mounting the magnet in the receiver component according to the present invention;

10 Figures 4, 4a and 4b depict yet further arrangements for mounting the magnet in the receiver component according to the present invention;

Figures 5a and 5b depict an alternative arrangement for mounting the magnet in the receiver component according to the present invention;

15

Figures 6a and 6b depict another arrangement for ensuring magnetic alignment of the receiver component with the external transmitter component;

20 Figures 7a and 7b depict still further arrangement for mounting the magnet in the receiver component according to the present invention;

Figures 8a and 8b depict an arrangement in which the receiver coil can be disconnected from the stimulator component; and

25 Figures 9a, 9b, 10 and 11 depict various arrangements for retaining the magnet in the receiver component using one or more manipulable clips.

Preferred Mode of Carrying out the Invention

30 Embodiments of a magnetic alignment system according to the present invention are generally depicted in the accompanying drawings as part of a cochlear implant system.

35 The magnetic alignment system 10 comprises an external transmitter unit 11 and an implantable receiver component 12.

The external transmitter unit 11 comprises a transmitter coil 13 which transmits electrical signals to the implantable receiver component 12 via a radio frequency (RF) link.

5 The implantable receiver component 12 of the system comprises a receiver coil 14 for receiving power and data from the transmitter coil 13 and a stimulator unit 15 within a housing 16. A cable 17 extends from the stimulator unit 15 to the cochlea and terminates in an electrode array 18. The signals received are applied by the array 18 to the basilar membrane 19 thereby stimulating the auditory nerve 20.

10

The receiver coil 14 typically comprises a wire antenna coil comprised of at least one and preferably two turns of electrically insulated platinum or gold wire.

15 The implantable receiver component 12 has a magnet to allow transcutaneous alignment of the external transmitter unit 11 (which also has a magnet) and the implantable receiver component 12.

20 The electrical insulation of the antenna coil is provided by a flexible silicone moulding. In use, the implantable receiver component 12 can be positioned in a recess of the temporal bone adjacent the ear of an implantee.

25 Arrangements for preventing any or at least relatively substantial movement of the magnet of a transcutaneous transmitter/receiver system, such as a cochlear implant system, whilst a recipient is undergoing MRI scans of relatively low field strengths whilst also allowing removal of the magnet from within the implantee if necessary, such as when the recipient is to undergo MRI scans of relatively high field strengths, are depicted in the drawings.

30 In Fig. 2, the magnet (here depicted as 51) of the implantable receiver component is housed within a suitable biocompatible flexible silicone mounting 52. The mounting 52 has a circular indentation 53 formed therein that serves to assist in identifying the location of the magnet 51 within the mounting 52. During surgery to remove the magnet 51, the ring 53 will indicate to the surgeon the location of the magnet 51 within the mounting 52. The indentation can also serve as a guide to a 35 scalpel blade used to cut through the mounting 52 to access the magnet 51.

In another embodiment depicted in Figs. 3a and 3b, the indicia can comprise two or more holes 54 formed in the silicone. The holes 54 again act as guides to a surgeon having to cut the magnet 51 from the mounting 52. That is, they identify where the mounting 52 should be cut to allow removal of the magnet 51 held therein.

5

In Fig. 4, the outer surface of the magnet 61 has a screw thread 62 formed therein that is engageable with a complementary thread 63 formed in a mounting ring 64 within the implantable component body (here depicted as 65). The mounting ring 64 can be made of a metal, ceramic or plastics material while the body 65 can be 10 formed from a suitable biocompatible material, such as silicone.

As depicted, a top surface of the magnet 61 can have a slot 66 formed therein that can receive a tool, such as a screwdriver or the like, to facilitate turning of the magnet and its removal from the mounting ring 64.

15

Fig. 4a shows an alternative embodiment of the present invention which is a variation of the embodiment shown in Figure 4. In this embodiment, the magnet 61 is provided with a pedestal element 61a for securing within the mounting element 64. In the depicted embodiment, the mounting element 64, is substantially trapezoidal in 20 shape with two upright walls 64a, being curved in configuration. The pedestal element 61a of the magnet 61 has a similar shape to that of the mounting element 64, namely has a shape consisting of two substantially parallel sides joined at both ends by curved portions. The pedestal is remote from the bottom face of the magnet 61, thereby forming a space between the pedestal element 61a and the magnet 61. The inner 25 surfaces of the upright walls 64a of the mounting element 64 can be provided with a recess to receive the curved end portions of the pedestal element 61a when the pedestal is placed within the mounting element 64 for engagement.

In this regard, the magnet 61 is rotated preferably 90 degrees to the position 30 shown in Fig. 4a for locating within the mounting element 64. Once the magnet 61 is placed in position with the pedestal element 61a located between the walls 64a of the mounting element 64, the magnet is then rotated 90 degrees such that the curved walls of the pedestal element 61a are received within the recessed curved walls of the mounting element 64. In this regard, the magnet is secured in place and is fixed within 35 the mounting element 64 as shown in Fig 11b. To remove the magnet 61 from the mounting element 64 in the event, for example, of an MRI procedure, the magnet 61 is

rotated such that the pedestal element 61a is no longer held in place within the walls 64a of the mounting element. The magnet can then be easily removed. A screwdriver or other such tool can be used to assist in this procedure, via the slot 66.

5 As is shown in Fig. 4a and 4b as the dotted line and the hashed area respectively, the magnet 61 and mounting element 64 are preferably secured in a flexible biocompatible material such as silicone. In this regard, the silicone can be arranged so as to overlap the walls of the mounting element 64 such that when the magnet 61 is placed in position for securing, as described above, the surrounding 10 material may be compressed between the magnet 61 and the mounting element 64. In this regard, the compression force may aid in securing the magnet in place when rotated into the secured position. Further, such an arrangement may further seal the arrangement from the ingress of body fluids into the mounting element 64.

15 Figs. 5a and 5b depict a still further arrangement wherein the magnet 71 of the implantable receiver component is housed within a pocket 72 formed in a wall of the biocompatible flexible mounting. The pocket 72 has a restricted opening 73 formed therein through which the magnet 71 can be inserted but which is sized to retain the magnet 71 within the pocket 72 during normal use.

20 Figs. 6a and 6b depict a still further arrangement according to the present invention. In this arrangement, the external transmitter unit (not depicted in Figs. 6a and 6b) has a magnet positioned therein while the implantable receiver component (here depicted as 80) has a conical magnetised insert 81 positioned therein to allow 25 transcutaneous alignment of the external transmitter unit and the implantable receiver component. The magnetised insert 81 of the implantable receiver component has a first end and a second end and increases in width away from the first end towards said second end, the first end being adapted to be positioned closer to the skin of the recipient to ensure self-centring of the magnet of the external transmitter unit with the 30 magnetised insert 81 of the receiver component.

The magnetised insert 81 can be mounted in a non-magnetic support within the receiver component. In one embodiment, the support can be a titanium case 82 as depicted in Fig. 6b. In another embodiment, as depicted in Fig. 6a, a suitable non-35 magnetic material, such as plastic, ceramic or titanium, stop member 83 can lock the insert 81 in the receiver component.

While the insert 81 can be removable, the use of a magnetised insert 81 rather than a magnet has the advantage of reducing the magnetic force on the receiver component during an MRI scan if it is left in place.

5

In Figs. 7a and 7b, the magnet 91 of the implantable receiver component (here depicted as 92) is housed within a recess 93 formed in a suitable biocompatible flexible mounting. The recess 93 is adapted to be located adjacent the skull 94 of the recipient in use thereby ensuring the magnet 91 is held in the recess 93 between the receiver component 92 and the skull 94 of the recipient.

10 In this embodiment, the magnet 91 can be removed from the recess by incising the skin of the recipient and then gently lifting the receiver component 92 away from the skull a distance sufficient to allow a surgeon to reach under the receiver component 15 and remove the magnet 91 from the recess 93, as is depicted in Fig. 7b.

Figs. 8a and 8b depict a further arrangement in which the mounting 101 housing the receiver coil 102 and magnet 103 is detachably connectable to an implantable tissue stimulator device (here depicted as 104). Electrical connection is made between the 20 coil 102 and the circuitry of the tissue stimulator device 104 by a pin and socket arrangement 105. Once connection is made, the pin and socket arrangement is preferably constructed such that there is no ingress of bodily fluids into either the stimulator device 104 or the mounting 101. In one embodiment, the socket can be mounted to the stimulator device and the pin or pins to the receiver component. An 25 arrangement where the socket is part of the receiver component and the pin or pins are part of the stimulator device can be equally envisaged.

If the recipient is to undergo an MRI scan, an incision can be made in the recipient, and the mounting 101 detached from the tissue stimulator device 104. The 30 mounting 101 is then removed rather than just the magnet 103. Once the MRI scan is complete, the mounting 101 can be re-implanted and the necessary connection again made between the coil 102 and the stimulator device 104.

35 In Figs. 9a, 9b, 10 and 11 various systems that rely on one or more clips to removably hold the magnet within the receiver component are depicted.

As depicted in Fig. 9a, a compression clip 111 can be used to compress a silicone pocket 112 around a magnet (here depicted as 113). The clip 111 can be removed by a surgeon if removal of the magnet 113 is required.

- 5 In the embodiment depicted in Fig. 9b, two clips 114 can be mounted on the magnet 113 and are engageable with a socket 115 in the receiver component (here depicted as 116). Alternative arrangements for using clips to retain the magnet 113 in the receiver component are depicted in Figs. 10 and 11.
- 10 As described, the various magnetic alignment system described herein are preferably part of a cochlear implant system wherein the external transmitter unit is positioned on the side of the recipient's head and wherein the implantable receiver component is positioned subcutaneously and in alignment with the external transmitter unit. The alignment systems are constructed so as to enable a recipient to undergo an
- 15 MRI procedure without removing the magnet of an implant, such as a cochlear implant. Such a system is particularly useful for those recipients requiring regular MRI scans.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific

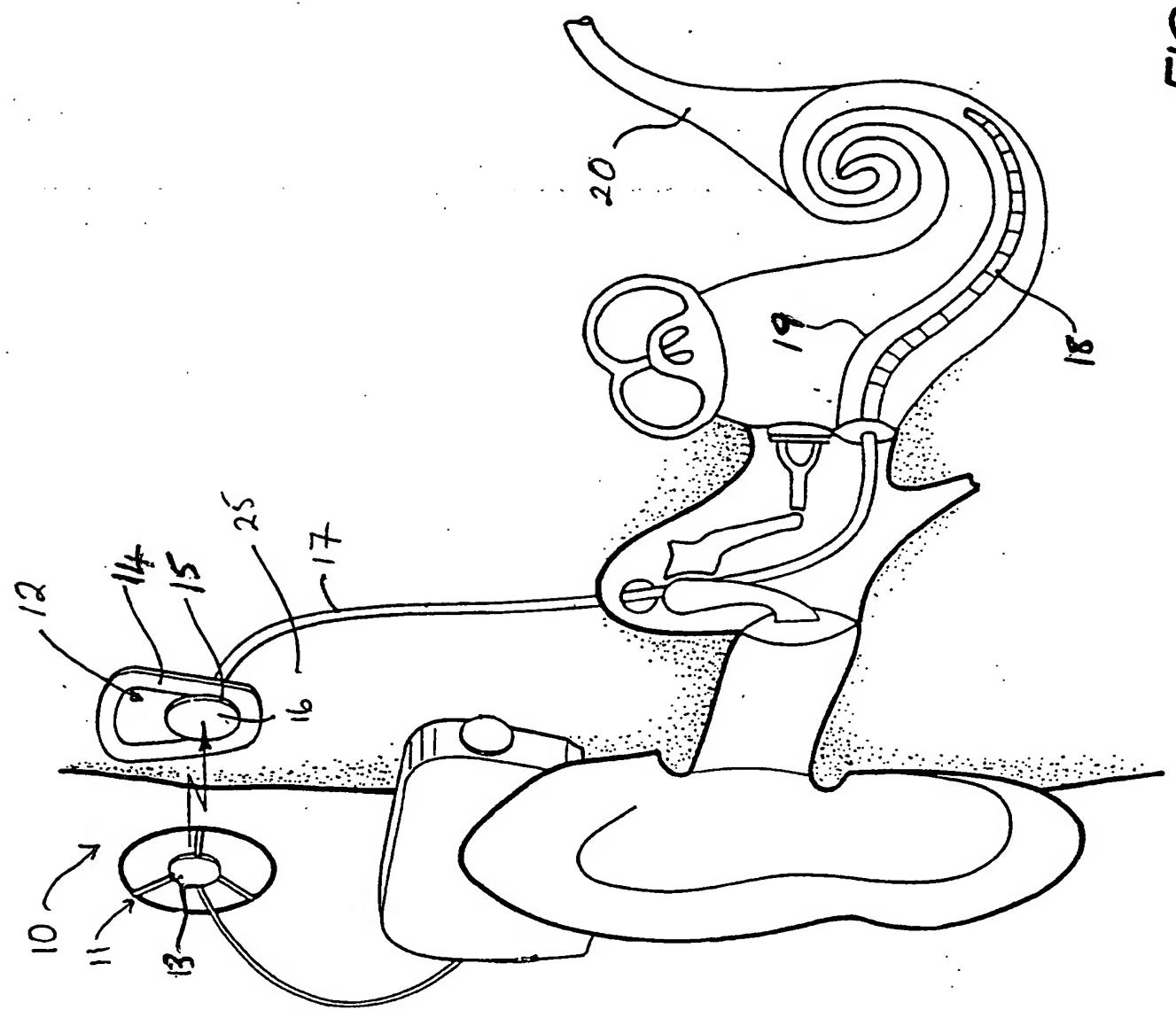
- 20 embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this ninth day of April 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

FIG. 1



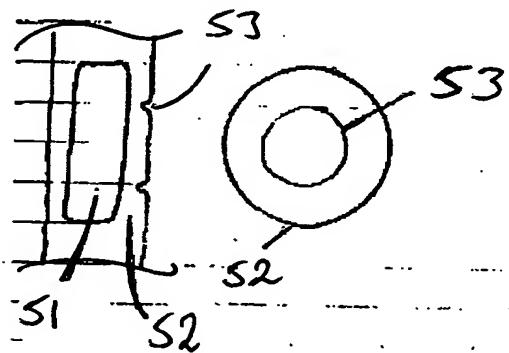


Fig. 2

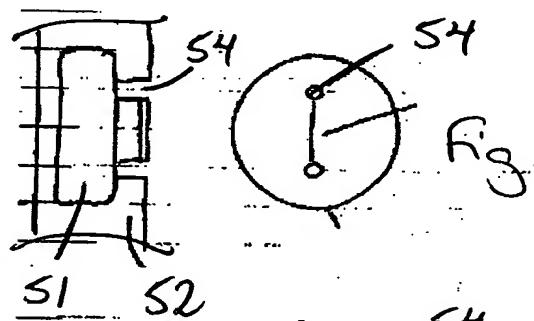


Fig. 3a

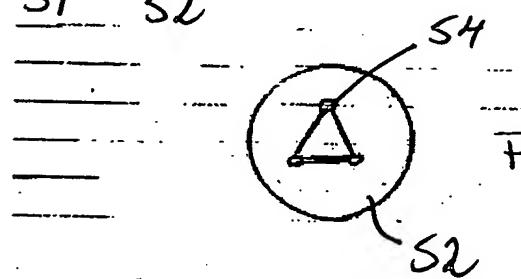


Fig. 3b

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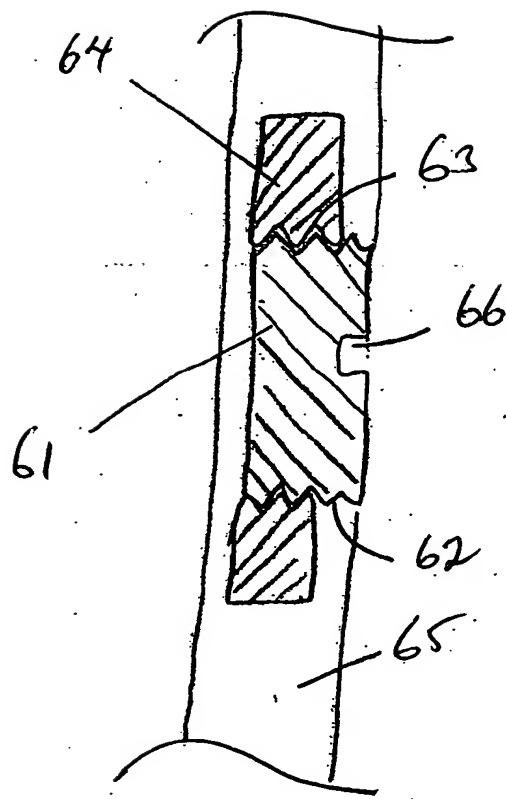


Fig. 4

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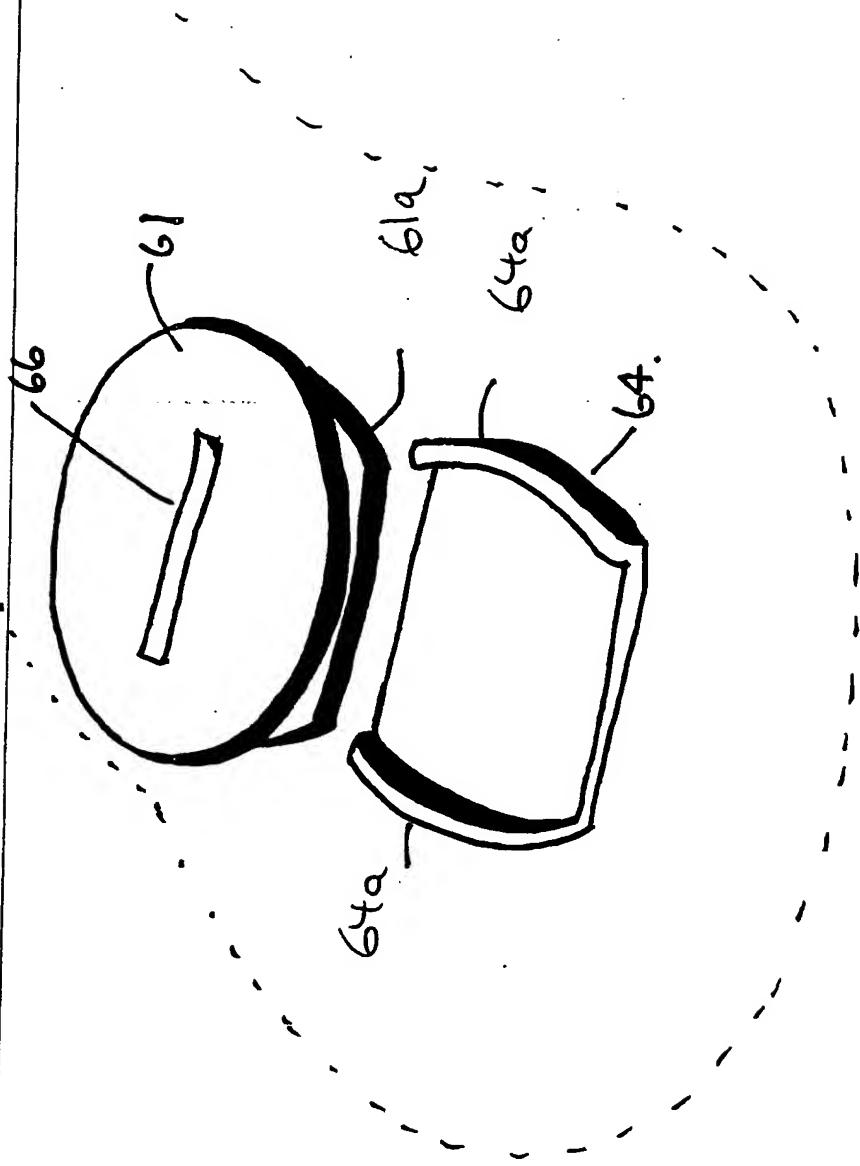
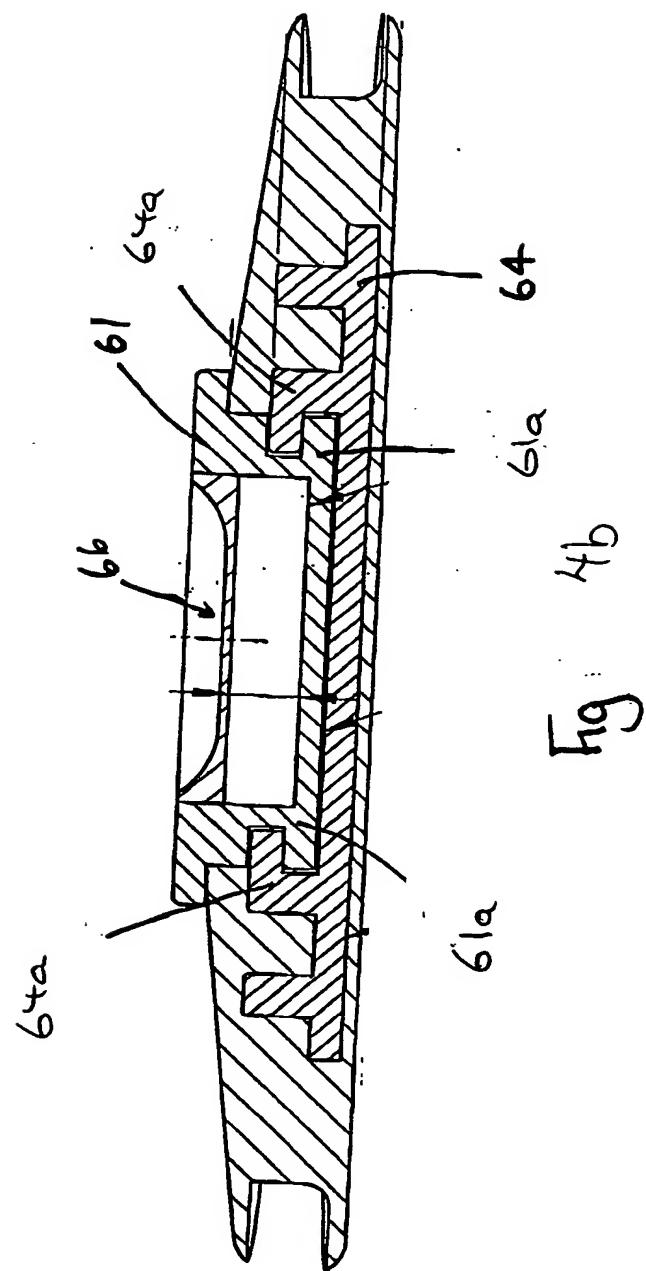
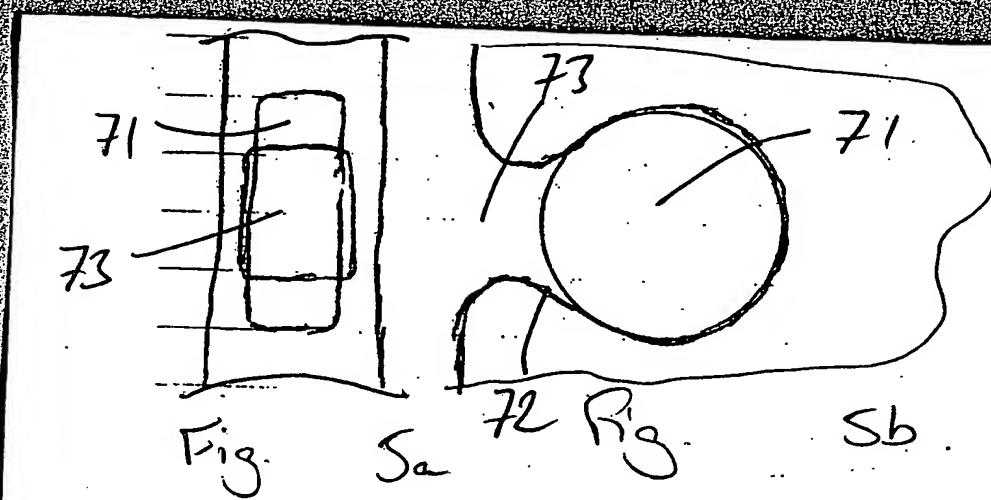


Fig 4a

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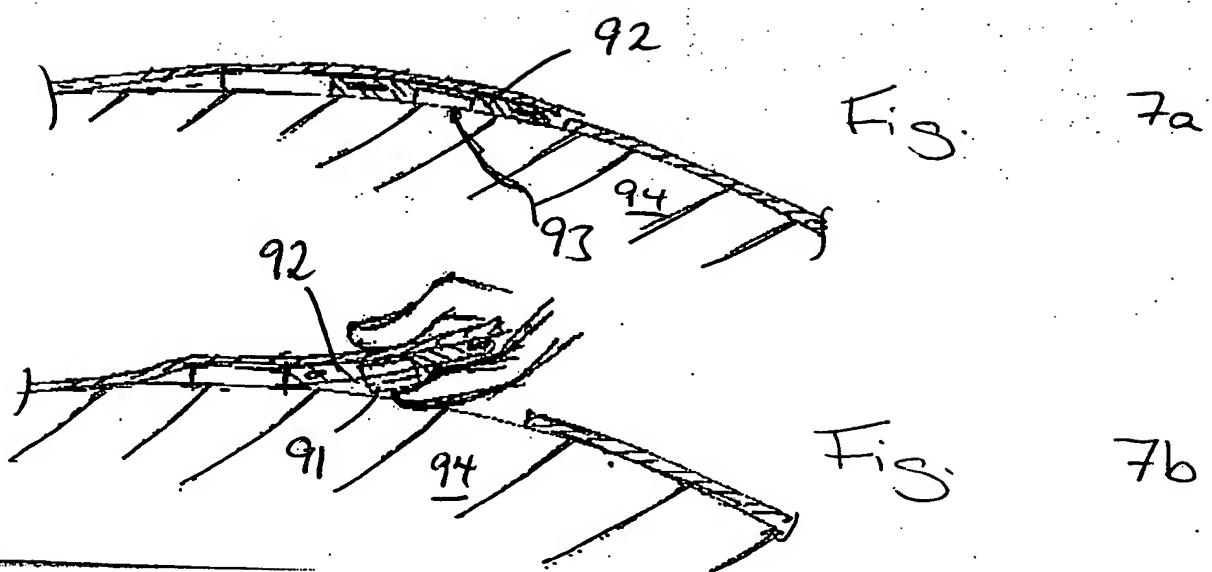
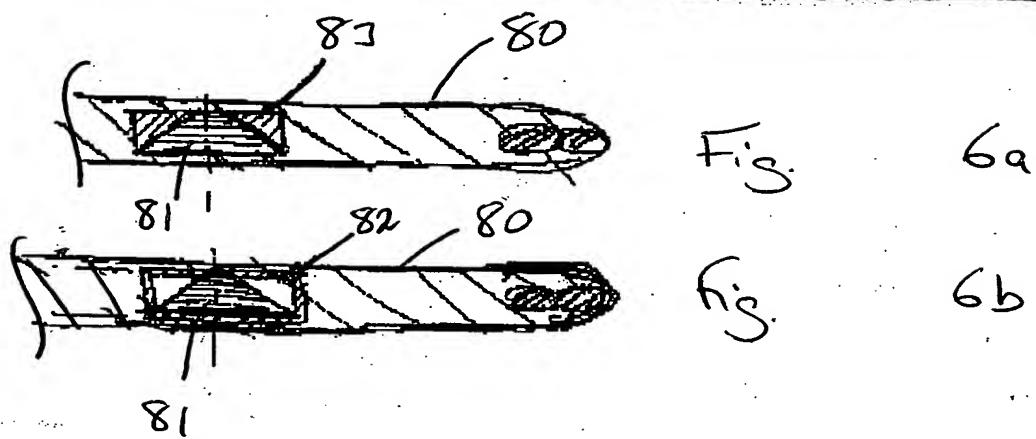


Fig. 8a

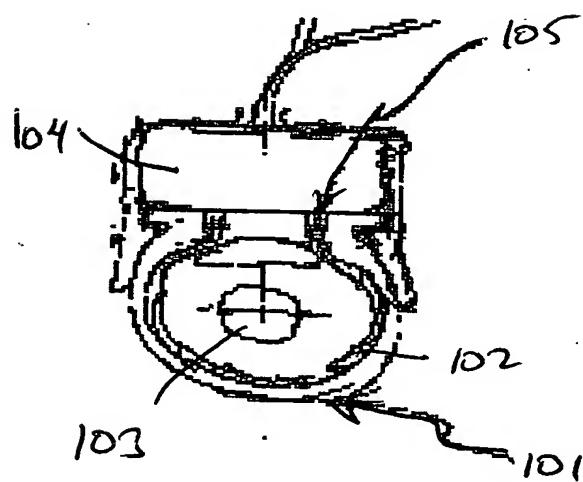
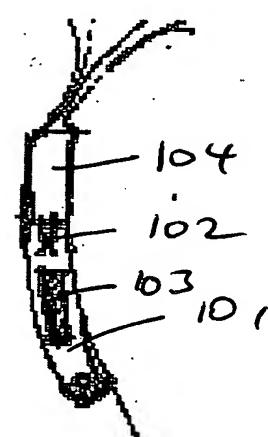


Fig. 8b



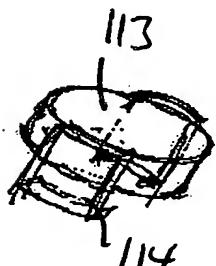
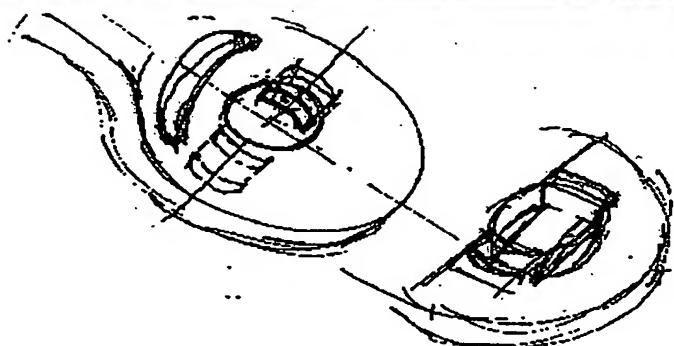


Fig.

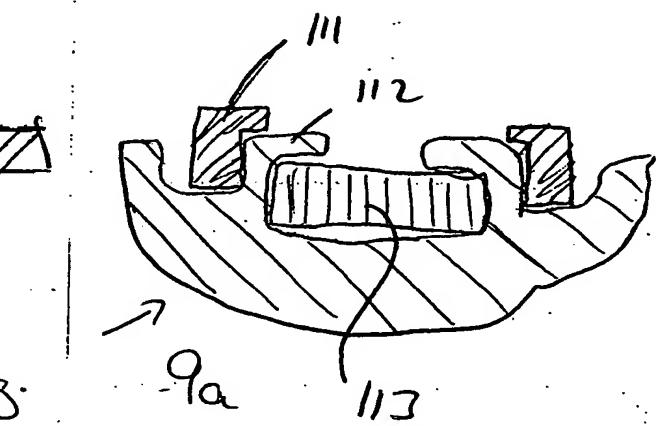


Fig.

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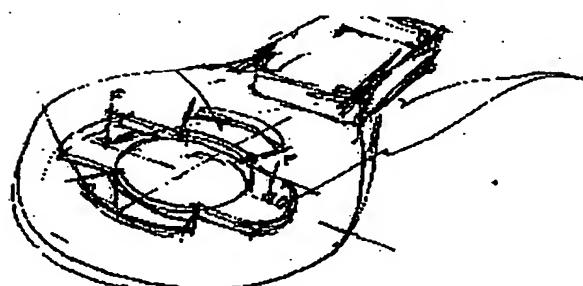
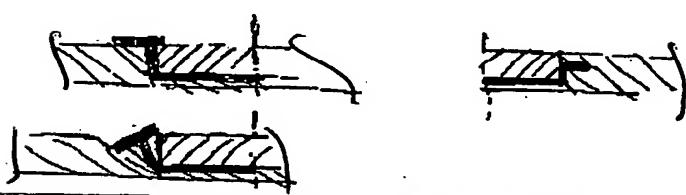
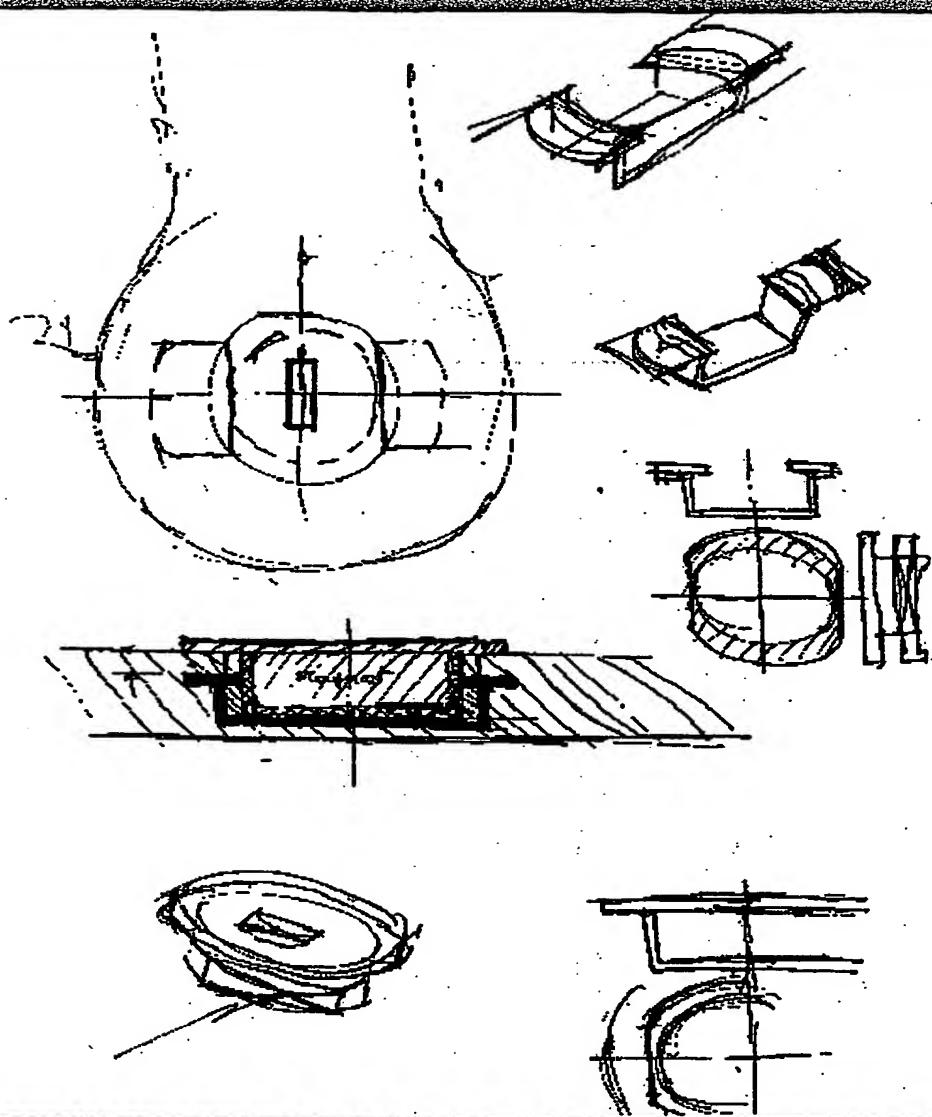


Fig.

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Fig. II